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Department of
Agriculture

Food Safety
And Inspection
Service

Technical
Service
Center

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AUDIT REPORT FOR NICARAGUA JUNE 19 THROUGH JUNE 28, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Nicaragua's meat inspection system from June 19 through June 28, 2001. All three establishments certified to export meat to the United States were audited. These establishments were slaughter and processing facilities.

The last audit of the Nicaragua meat inspection system was conducted in September 2000. Three establishments were audited (04, 05 and 08) and all were acceptable.

During calendar year 2001 (up to 6-30-01), Nicaragua exported 14,841,844 pounds of fresh beef and beef products, beef edible organs, and beef processed products to the U.S. Port-of-entry (POE), rejections were 20, 557 pounds for processing defects, miscellaneous defects, contamination, pathological defects, and transportation damage and missing shipping marks. At the time of audit, Nicaragua was exporting beef and beef products only.

At the time of the 2000 audit, Nicaragua's meat inspection system was found to have effective controls to ensure that product destined for the United States was produced under conditions equivalent those that FSIS requires in domestic establishments.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Nicaragua's national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection offices of the facilities of the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella* and *E. coli*. Nicaragua uses government laboratories for microbiological testing.

Nicaragua's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program; and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all three establishments audited (04, 05 and 08). Details of audit findings and observations, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

Entrance Meeting

On June 19, 2001, an entrance meeting was held at the offices of the Ministerio Agropecuario y Forestal (MAG-FOR) at Managua, Nicaragua and was attended by Drs. Eduardo Sacasa Urcuyo, Director General; Omar Garcia, Director, Animal Health; Leyia Umana, Director of National Laboratory of Biological Residues; Sonia Garcia, Director of National Laboratory of Veterinary Diagnostic; Lisandro Herrera, Area Chief of Meat Inspection Services; Pedro Blandon, Area Chief, Meat Inspection Division; Mr. Diego Velasquez Pereira, Chief Meat and Poultry Inspection Services; Mrs. Maria Soler, Interpreter and Dr. Suresh Singh, International Audit Staff Officer of the Technical Service Center, Food Safety and Inspection Service (FSIS-USDA). Topics of discussion included the following:

1. Travel arrangements and itinerary within Nicaragua.
2. Briefing of status of recent correspondence between FSIS and MAG-FOR.

Headquarters Audit

There had been a few changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of the Nicaragua inspection system in September 2000. Mr. Diego Pereira is the new Chief of Meat, Poultry and Seafood Inspection of Nicaragua and two regions in the country were created and are headed by Drs. Lisandro Herrera and Pedro Blandon.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews and audits for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This record review was conducted at the establishments during on-site visits. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Supervisory visits to establishments that were certified to export to the U. S.
- Training records for inspectors.
- Label approval records such as generic labels
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials and veterinary coverage.
- Export product inspection and control including export certificate
- Enforcement records, including examples of criminal procedures, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Nicaragua as eligible to export meat products to the United States were full-time, MAG-FOR employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Three establishments were certified to export meat products to the United States at the time this audit was conducted. All three establishments were visited for on-site audits. In all establishments visited, both Nicaraguan inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Government (MAG-FOR) of Nicaragua Residues Laboratory in Managua was audited on June 28, 2001. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation, print outs, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable.

Nicaragua's microbiological testing for *Salmonella* and *E. coli* was being performed in government laboratories and the procedures and methodology were acceptable.

Establishment Operations by Establishment Number

The following operations were being conducted in the three establishments:

Beef slaughter, cutting, and boning - two establishments (0004 and 0005)
Beef slaughter, cutting and boning (no production) – one establishment (0008). This establishment was not operating due to financial problems.

SANITATION CONTROLS

Based on the on-site audits of establishments, Nicaragua's inspection system had controls in place for basic establishment facilities, condition of facilities equipment, product protection and handling and establishment sanitation program except, hand washing facilities in lavatories were not provided with running hot water as required in CFR-9, Part 416.2-h2 in all three establishments. The floors in the hallways of the freezers were in need of repairs in Establishment 5.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements with only occasional minor variations.

Cross-Contamination

In all three establishments, a white powder was being used on cryovac bags and accumulation was observed on the packaging table. Establishment officials did not know what the material was. Later it was discovered that it was a food grade cornstarch used in the layers of cro-vac bags from manufacturer. Veterinary officials obtained the letter of guarantee and composition of substance from Cro-Vac Corporation from Guatemala by fax immediately.

ANIMAL DISEASE CONTROLS

Nicaragua's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. Nicaragua's Veterinary Officials certified that no FMD and BSE are present in the country. Two cattle ranches were visited to observe the animal husbandry practices in this audit.

RESIDUE CONTROLS

Nicaragua's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Nicaragua inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. In this audit, a special in-depth review of Nicaragua's residue control program was done by using audit check list and a feed mill and veterinary pharmaceutical store were visited to observe the controls of feed medications and veterinary drug sales. The Government of Nicaragua has good, strict guidelines for the controls of feed additives and veterinary drugs.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Nicaragua's inspection system had controls in place to ensure adequate product protection and processed product controls. Knife at rectum station was not being sterilized properly after each carcass and evisceration portable table was not being cleaned and sterilized by hot water in Establishments 4 and 8.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program and met FSIS requirements. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements.

Testing for Generic *E. coli*

All of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Nicaragua has adopted the FSIS regulatory requirements for generic *E. coli* testing.

Additionally, establishments had adequate controls in place to prevent meat products intended for Nicaragua's domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The Nicaragua inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat re-inspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

All of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program and criteria used in the equivalency determination. The data collection instrument used accompanies this report (Attachment D).

Nicaragua has adopted the FSIS regulatory requirements for *Salmonella* testing.

Species Verification Testing

At the time of this audit, Nicaragua was not exempt from the species verification testing requirements. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by Nicaragua's National Meat Inspection officials. All were veterinarians with at least 10 years of experience in meat inspection.

The internal review program was applied equally to both export and non-export establishments to the U.S. Internal review visits were announced in advance, and were conducted at least once monthly. The records of audited establishments were kept in the inspection offices and copies were also kept in National Meat Inspection offices at Managua, and routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, it is delisted for U.S. export. The Chief Meat Inspection Officer is empowered to conduct an in-depth review and take proper corrective actions and preventive measures before export activities to the United States can resume.

Enforcement Activities

Meat Inspection officials carry out enforcement activities. The Chief of Meat and Poultry Inspection Services has the sole power to initiate all enforcement actions.

Exit Meetings

An exit meeting was conducted in Managua on June 28, 2001. The participants included Dr. Omar Garcia, General Director, Animal Health; Dr. Leyla Umana, General Director, National Laboratory Residues; Dr. Lisandro Herrera and Dr. Pedro Blandon, Area Chief of Meat Inspection; Mr. Diego V Pereira Chief, Poultry and Meat Inspection; Mrs. Maria K Soler, translator and Dr. Suresh Singh, International Audit Staff Officer, USDA, FSIS.

The following topics were discussed:

1. Audit findings and observations of the auditor as reported in this report.
2. Enforcement reports of USDA were given to the inspection officials and requested the same type of enforcement report from Nicaraguan authorities.

Additionally, Mr. William W. Popp, Economic Officer and Mrs. Clare Creegan Chamorro, Agriculture Specialist of American Embassy in Managua were briefed regarding Nicaragua's meat inspection audit findings.

CONCLUSION

The inspection system of Nicaragua was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Three establishments were audited and all were acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Suresh P. Singh
International Audit Staff Officer

(signed)Dr. Suresh P. Singh

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (*no comments received*)

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. Identified	7. Documentation done daily	8. Dated and signed
04	√	√	√	√	√	√	√	√
05	√	√	√	√	√	√	√	√
08	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10. Adequate verific. Procedures	11. Adequate documentation	12. Dated and signed
04	√	√	√	√	√	√	√	√	√	√	√	√
05	√	√	√	√	√	√	√	√	√	√	√	√
08	√	√	√	√	√	√	√	√	√	√	√	√

Data Collection Instrument for Generic *E. coli* Testing

Each establishment ~~was~~ evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The equivalent carcass site and collection methodology (Swab) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method .
9. The results of the tests are being recorded on a process control chart but on a table form showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predominant Species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
04	√	√	√	√	√	√	√	√	√	√
05	√	√	√	√	√	√	√	√	√	√

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The equivalent carcass site and method is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
04	√	√	N/A	√	√	√
05	√	√	√	√	√	√